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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,039	07/12/2001	Shoulian Dong	3218.2A	3123

22886 7590 05/13/2005

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SANTA CLARA, CA 95051

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,039

Applicant(s)

DONG ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-53, 57, 58 and 174-177 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57, 58 and 174-177 is/are allowed.
- 6) ☒ Claim(s) 39-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15, 2005 has been entered.

Preliminary Remark

Cancellation of claims 1-38, 54-56, and 59-173 and addition of claims 174-177 are acknowledged.

With regard to claim 58, reciting the term, "Class IIs endonuclease," Applicants are advised that claims 49 and 174 recite the term, "type IIs endonuclease." For the purpose of claim term consistency, the phrase, "type IIs endonuclease" is also suggested for claim 58.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

(H) Breadth of the claims: Independent claim 39 (and their dependent claims 40-53) recites the phrase, “providing an array, wherein a computer system is used to *identify polymorphisms that are predicted to be present on fragments that are amplified when the first nucleic acid sample is fragmented by said selected fragmentation method and amplified by said selected amplification.*” The claim, thus, is drawn to identifying polymorphisms that have been predicted to be present on a nucleic acid sample which have been treated with a particular fragmentation and amplification step.

(E) State of Prior Art: To date, a technology which allows a computer to predict whether a particular polymorphism is present or not on a nucleic acid sample, has not been presented. All technologies of the prior art requires that the empirical experimentation be conducted in order to identify whether a particular polymorphism is present or absent in a nucleic acid sample. For example, Chee et al. (WO 95/11995, published May 4, 1995) demonstrate a method of identifying mutations (including polymorphisms) by providing an array comprising a plurality of probes containing mutations and a plurality of reference probes containing wildtype sequences, wherein the actual hybridization is performed (*i.e.*, the need for empirical determination) in order to identify whether or not a test sample contained a particular mutation (including

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polymorphism) (see page 2, lines 16-20 and 27-29; page 4, lines 10-24; page 5, lines 8-10), wherein artisans explicitly state that, “[t]he identity of the target sequence is deduced from the pattern of hybridization intensities.” (page 5).

(B) Amount of Guidance: Neither the prior art or the instant specification gives guidance toward being able to predict whether a particular polymorphism(s) is present or absent on a target nucleic acid without empirical determination.

(C) Absence of Working Example: The instant application does not have any example which pertains to this embodiment.

(D) Unpredictability: As discussed in the state of prior art, the determining whether or not a target nucleic acid contains a particular polymorphism or polymorphisms requires an empirical determination as predication without experimentation remains unpredictable.

(F) Skill level: The relative skill level of the artisan is considered to be high.

(A) Quantity of experimentation: The experimentation required by a skilled artisan would amount to be undue in endeavoring to predict whether a particular polymorphism is present or not in a sample target nucleic acid, without actual experimentation.

It is determined that the invention as claimed would require undue experimentation of a skilled artisan given the state of art as well as the absence of guidance/working examples in the instant specification that would reasonable allow said skilled artisan to predict the presence or absence of a particular polymorphism from a sample by use of a computer without conducting the actual experimentation.

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Applicants are advised that claims as amended are not enabled, and thus art rejection has not been applied in accordance with MPEP 2121.01 which requires that prior art being applied be enabling/operable.

Upon amendment to overcome the rejection under this section, if applicable, the claims would be rejected over prior art and be made Final, finality being necessitated by Amendment (MPEP 706.07(a)).

Claim Rejections - 35 USC § 103

The rejection of claims 39-53 under 35 U.S.C. 103(a) as being unpatentable over McCaskey (U.S. Patent No. 6,100,030, issued August 8, 2000, priority January 10, 1997) in view of DeRisi et al. (Science, October 1997, vol. 278, pages 680-686) and Moyer et al. (Applied and Environmental Microbiology, July 1996, vol. 62, no. 7, pages 2501-2507), made in the Office Action mailed on December 15, 2004 have been withdrawn in view of the Amendment received on April 15, 2005, based on careful consideration of the claims.

Conclusion

Claims 39-53 are rejected.

Claims 57, 58, and 174-177 are free of prior art.

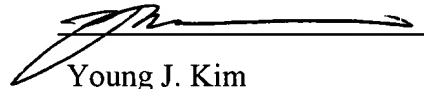
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

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If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
5/12/05

**YOUNG J. KIM
PATENT EXAMINER**

yjk